



PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:

ETTER

Serial No.: 10/717,429

Filed: November 19, 2003

Confirmation No.: 7009

Atty. File No.: 42830-10009

For:

"PARTICULATE DRUG-CONTAINING PRODUCTS AND METHOD OF

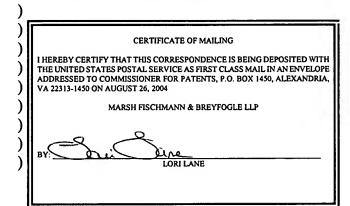
MANUFACTURE"

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

) Group Art Unit: 1614)) Examiner: Not yet assigned

INFORMATION DISCLOSURE STATEMENT



Pursuant to Applicant's duty of disclosure under 37 CFR § 1.56 and 37 CFR §§ 1.97-1.98, Applicant hereby submits the enclosed PTO Form 1449, although Applicant does not admit that any of such documents, alone or in any combination, is considered to be material to patentability as defined in 37 CFR § 1.56(b). Moreover, the inclusion of these documents is not to be construed as an admission by Applicant that each such document is prior art as to the above-identified application. Pursuant to the Official Gazette Notice of August 5, 2003, copies of any U.S. Patents or published U.S. Patent Applications are not being submitted herewith.

Attorney Docket No.: 42830-10009

PATENT APPLICATION

Copies of any foreign patent and non-patent documents are submitted herewith. No fees are believed to be due with this communication, however, please charge any required fees to deposit account 50-1419.

Respectfully submitted,

MARSH FISCHMANN & BREYFOGLE LLP

Date: August 10, 800 4

By:

Řené A. Pereyra

Registration No. 45,800

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Aurora, Colorado 80014 Telephone: (303)338-0997 Facsimile: (303)338-1514

ТRA	TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT Option 37 CFR 1.97(b) or 1.97(c)) Docket No. 42830-10009									
	In Re Application Of: AUG 3 0 2004									
	Serial No. Filing Date Examiner Group Art Unit									
1	0/717,429	November 19, 2003	Not yet assigned	1614						
Title:			-							
"PAR	TICULATE DRUG	G-CONTAINING PRODUCTS AN	ND METHOD OF MANUFACT	TURE"						
		Commiss P.C	ddress to: sioner for Patents D. Box 1450 a, VA 22313-1450							
		37 C	FR 1.97(b)							
1. 🛚	of a national ap three months of application; befo	Disclosure Statement submitted plication other than a continued the date of entry of the national ore the mailing of a first Office Actiling of a request for continued expenses.	prosecution application under stage as set forth in 37 CFR tion on the merits, or before th	r 37 CFR 1.53(d); within 1.491 in an international ne mailing of a first Office						
		37 C	CFR 1.97(c)							
2. 🗆	CFR 1.97(b), pr Final Action un	Disclosure Statement submitted to vided that the Information Disc der 37 CFR 1.113, a Notice of sprosecution in the application, a	closure Statement is filed before for the file of the	ore the mailing date of a						
	☐ the staten	nent specified in 37 CFR 1.97(e)	;							
		OR								
	☐ the fee se	et forth in 37 CFR 1.17(p).								
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SURE STATEMENT (c))	Docket No. 42830-10009							
Examiner	Group Art Unit							
Not yet assigned	1614							
"PARTICULATE DRUG-CONTAINING PRODUCTS AND METHOD OF MANUFACTURE"								
ent of Fee								
(Only complete if Applicant elects to pay the fee set forth in 37 CFR 1.17(p)) ☐ A check in the amount of is attached. ☐ The Director is hereby authorized to charge and credit Deposit Account No. 50-1419 as described below. ☐ Charge the amount of ☐ Credit any overpayment. ☐ Charge any additional fee required. ☐ Certificate of Transmission by Facsimile* ☐ Certificate of Mailing by First Class Mail ☐ I certify that this document and authorization to charge deposited account is being facsimile transmitted to the United States Patent and Trademark Office (F: ☐ Certificate of Mailing by First Class Mail ☐ I certify that this document and fee is being deposited on August 26, 2004 with the U.S. Postal Service as first class mail under 37 C.F.R. 1.8 and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.								
Signature of Person Mailing Correspondence								
LORI LANE								
Typed or Printed Name of Person	n Mailing Certificate							
*This certificate may only be used if paying by deposit account. *Signature Dated: August 36, 3004 Reiné A. Pereyra Registration No. 45,800 Marsh Fischmann & Breyfogle LLP 3151 South Vaughn Way, Suite 411 Aurora, Colorado 80014 Phone: (303) 338-0997 Facsimile: (303) 338-1514								
	Examiner Not yet assigned METHOD OF MANUFACTURE Int of Fee Is to pay the fee set forth in 37 CFR 1.1 Ited. Ited. Ited. Ited: Ited: Iterify that this document and fon August 26, 2004 with the as first class mail under 37 addressed to the Commissioner 1450, Alexandria, VA 22313-145 Signature of Person Mail LORI LANE Typed or Printed Name of Person							

Docket Number (optional)	Application Number
42830-10009	10/717,429
Applicant(s)	
ETTER	
Filing Date	Group Art Unit

(Use several sheets if necessary)

November 19, 2003 1614

U.S. PATENT DOCUMENTS								
*EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING I IF APPROPI	
	1.	4,895,719	01/23/1990	RADHAKRISHNAN ET AL.	424	45		
	2.	5,460,173	10/24/1995	MULHAUSER ET AL.	128	203.15		
	3.	5,503,869	04/02/1996	VAN OORT	427	2.14		
	4.	5,619,984	04/15/1997	HODSON ET AL.	128	203.15		
	5.	5,639,441	06/17/1997	SIEVERS	424	9.3		
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	7.	5,770,559	06/23/1998	MANNING ET AL.	514	2		
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	9.	5,795,594	08/18/1998	YORK	424	489		
	10.	5,814,678	09/29/1998	RANDOLPH	522	18		
	11.	5,851,453	12/22/1998	HANNA ET AL.	264	5		
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	Α.	0 069 715 B1	11/05/1986	Europe			ILS	NO.
	В.	0 542 314 A1	05/19/1993	Europe				
	c.	0 542 314 B1	07/01/1998	Europe				
•	D.	WO 95/01221	01/12/1995	WIPO				
	E.	WO 96/00610	01/11/1996	WIPO				
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	I.	Web Page www.allp.c	om/PulmoSpheres/I	pounds Administered by Inhalation Swhite.HTM; publication d	ate unknow	n		
	п.	Zia, Hossein et al., "C	omparison of Nasal	Insulin Powders Prepared by Suchnology, 15:273-301 (1997).	percritical l	Fluid and Fre	eze-Dry	ing
EXAMINER	•	<u> </u>		DATE CONSIDERED				

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application

INFORMATION DISCLOSURE CITATION (Use several sheets if necessary) ETTER Filing Date November 19, 2003 Application Number 10/717,429 Application Number Group Art Unit November 19, 2003

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	12.	5,874,064	02/23/1999	EDWARDS	424	46		
	13.	5,875,776	03/02/1999	VAGHEFI	128	203.15		
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	17.	6,372,260	04/16/2002	ANDERSSON ET AL.	424	501		
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	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	YES	N
	F.	WO 96/32149	10/17/1996	WIPO				
	G.	WO 98/04308	02/05/1998	WIPO				
	н.	WO 98/29141	07/09/1998	WIPO				
	I.	WO 98/36825	08/271998	WIPO				
	J.	WO 99/16419	04/08/1999	WIPO				
	1		OTHER	DOCUMENTS (Including Author	or, Title, Date, Pei	rtinent Pages, Et	c.)	
	III.	77:89-125 (1996)		of Microparticulates Using Su			harm. S	ci.,
	IV. Tom, Jean W. and Pablo G. Debenedetti, "Formation of Bioerodible Polymeric Microspheres and Microparticles by Rapid Expansion of Supercritical Solutions,; <i>Biotechnol. Prog.</i> , 1991, vol. 7, No. 5, pp. 403, 411.							
EXAMINER				DATE CONSIDERED				

Form PTO-A820 (also form PTO-1449)

		Docket Number (optional) 42830-10009	Application Number 10/717,429	
	INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)	Applicant(s) ETTER		
•		Filing Date November 19, 2003	Group Art Unit 1614	

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	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Trans		
-	К.	WO 99/59710	11/25/1999	WIPO			YES	NO_	
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	v.	Winters, Michael A. et	al., "Long-Term ar	nd High-Temperature Storage o	f Supercritica	ally-Processe			
		Microparticulate Prote Winters, Michael A. et	in Powders," <i>Pharm</i>	n. Res., vol. 14, No. 10, 1997, p of Proteins in Supercritical Car	pp. 1370-137 bon Dioxide,	8. '' J. Pharmac	eutical		
	VI.	Sciences, vol. 85, No.		6-594.	·				
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	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	YES	NO
•			OTHER DO	OCUMENTS (Including Author, T	itle, Date, Perti	nent Pages, Etc.)	
	VII.	Pharmaceutical Science	es, vol. 83, No. 12,	Characterization of Microparti Dec 1994, pp. 1651-1656.				
	VIII.	Yeo, Sang-Do et al., "I Biotechnology and Bio	Formation of Micropengineering, vol. 4	particulate Protein Powders Us 1, No. 3, Feb. 5, 1993, pp. 341-	ing a Superci	ritical Fluid A	ntisolve	ent,"
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